

NC Standing Order Template #2
JYNNEOS Vaccine Administration

Updated: August 11, 2022/ Revised December 9, 2022/Corrected December 14, 2022

This is a template for a standing order:

Purpose: To reduce morbidity and mortality from Orthopoxvirus (Mpx, Smallpox) by vaccinating individuals with JYNNEOS (SMALLPOX AND MPOX VACCINE, LIVE, NON-REPLICATING) vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis.

Policy: In addition to the approved standard subcutaneous regimen, on August 9, 2022, the FDA granted Emergency Use Authorization of JYNNEOS intradermal administration as an alternative to the subcutaneous route, as well as subcutaneous administration in those under 18 years of age.

As of 8/29/22, NC DHHS, in alignment with CDC guidance, requests that all providers administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. The only unique contraindication for intradermal injection is history/or presence of keloid scarring. If this contraindication does exist, then administer subcutaneously.

On 9/28/22, CDC release updated guidelines for the intradermal administration of JYNNEOS in adults and young children necessitating the revision of this standing order template.

On 10/12/22, NC DHHS expanded JYNNEOS eligibility criteria for pre-exposure vaccination in coordination with the CDC.

On 10/21/22, CDC revised their recommendation to providers re: seeking consultation with jurisdictional health department for administration of JYNNEOS from children 18 or less to children than 6 months of age.

On 12/9/22, NC DHHS rescinded their previous request to administer JYNNEOS intradermally to all adult recipients unless the client has a medical contraindication to the ID route. This decision was made considering the decreasing incidence of cases, adequate supply statewide of vaccine and to reduce all barriers to care, in alignment with CDC guidance. As of 12/9/22, Public Health Jurisdictions and health care providers should decide whether to offer the intradermal or subcutaneous regimen based on balancing optimal vaccination use and acceptance, feasibility of administration and available vaccine supply. Additionally, in response to the WHO and CDC request to refer to monkeypox as “mpox” in order to reduce any stigma associated with the virus, NC DHHS has revised this standing order template to refer to monkeypox as “mpox”.

Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Note: There is no change in product formulation. Dosage differs based on age of individual and vaccine administration route. Vials are preservative free. Unused vaccine will still need to be discarded 8 hours after the vial is first accessed. A 2nd dose is still required to be completely immunized. Please review (**alternative regimen**): [Fact Sheet For Healthcare Providers Administering Vaccine: Emergency Use Authorization Of JYNNEOS \(Smallpox And mpx Vaccine, Live, Non-Replicating\) For Prevention Of Mpx Disease In Individuals Determined To Be At High Risk For mpx Infection](#) and the package insert for [JYNNEOS \(Smallpox and mpx Vaccine, Live, Non-replicating\) suspension for subcutaneous injection \(standard regimen\)](#) prior to implementing this standing order.

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Condition or Situation	
Condition or Situation in Which the SO Will Be Used	<p>JYNNEOS is a vaccine indicated for prevention of smallpox and mpox disease in high-risk individuals. Based on agency directive on the day the patient presents the Standard Regimen or Alternative Regimen may be administered to patients 18 years of age or older. Patients less than 18 years of age shall ONLY receive the Standard Regimen. Patients who present requesting vaccination with JYNNEOS will receive:</p> <p>Primary Series STANDARD REGIMEN 18 years and older of age</p> <ul style="list-style-type: none">• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time. <p>NOTE: Two doses are required to be considered completely immunized.</p> <p>Primary Series LESS THAN 18 YEARS OF AGE</p> <ul style="list-style-type: none">• 2 subcutaneous injections (SQ) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time. <p>NOTE:</p> <ul style="list-style-type: none">• For individuals less than 6 months of age in need of JYNNEOS, please contact the Communicable Disease Branch’s Epi On-Call Line at 919-733-3419 for consultation prior to administration.• Two doses are required to be considered completely immunized. <p>Primary Series - ALTERNATIVE REGIMEN 18 years of age and older:</p> <ul style="list-style-type: none">• 2 intradermal injections (ID) separated by 28 days. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against mpox during this time. <p>Recommended 2nd dose minimum and maximum intervals See CDC interim clinical considerations for more information</p> <ul style="list-style-type: none">• Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP’s general best practices, a dose may be administered up to 4 days before the minimum interval of 28 days (known as the “grace period”), which would be a minimum of 24 days after the first dose.• The second dose of JYNNEOS vaccine should be given 28 days after the first dose but may be given up to 7 days later than the minimum interval (i.e., up to 35 days after the first dose).• If the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to Table 7. Vaccine Administration Errors and Deviations.• If 1st dose was administered subcutaneously, provide ID injection as 2nd dose, unless otherwise contraindicated. <p>NOTE:</p>

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	<ul style="list-style-type: none"> Persons with a history of keloid scarring should not receive this vaccine intradermally. Vaccinate subcutaneously following the instructions for subcutaneous vaccination below. Two doses are required to be considered completely immunized <table border="1" data-bbox="407 373 1398 663"> <thead> <tr> <th colspan="4">Standard and Alternative Dosing Regimens</th> </tr> <tr> <th>Age</th> <th>Route</th> <th>Dose</th> <th>Dosing Interval*</th> </tr> </thead> <tbody> <tr> <td>≥ 18 Standard Regimen</td> <td>Subcutaneous</td> <td>0.5 mL</td> <td>28 days</td> </tr> <tr> <td><18 Alternative Regimen</td> <td>Subcutaneous</td> <td>0.5 mL</td> <td>28 days</td> </tr> <tr> <td>People of any age who have a history of developing keloid scars</td> <td>Subcutaneous</td> <td>0.5 mL</td> <td>28 days</td> </tr> <tr> <td>≥ 18 Alternative Regimen</td> <td>Intradermal**</td> <td>0.1 mL</td> <td>28 days</td> </tr> </tbody> </table> <p>*Recommended minimum interval to 2nd dose is 28 days and a maximum interval 7 days later than the minimum interval (i.e., up to 35 days). There is no need to restart or add doses to the series if there is an extended interval between doses.</p> <p>** Requires use of a tuberculin syringe of 1/4 to 1/2 in in length and a 26- or 27-gauge needle.</p>	Standard and Alternative Dosing Regimens				Age	Route	Dose	Dosing Interval*	≥ 18 Standard Regimen	Subcutaneous	0.5 mL	28 days	<18 Alternative Regimen	Subcutaneous	0.5 mL	28 days	People of any age who have a history of developing keloid scars	Subcutaneous	0.5 mL	28 days	≥ 18 Alternative Regimen	Intradermal**	0.1 mL	28 days
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<p>Pre and Post-Exposure Prophylaxis</p>	<p>Administer JYNNEOS to persons who present requesting vaccination and self-attest to being in a high-risk category:</p> <p>JYNNEOS Eligibility Criteria</p> <ol style="list-style-type: none"> Anyone who had close contact in the past two weeks with someone who has been diagnosed with mpox (see CDC Exposure risk assessment); or Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days: or People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days. People who have had any of the following in the past 6 months: <ol style="list-style-type: none"> Sex at a commercial sex venue Sex in association with a large public event Sexual partners of people with the above risks People who anticipate experiencing the above risks Health care workers who were in the same room with or within 6 feet of a patient suspected or confirmed to have mpox during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection. <p>mpox vaccines are recommended for people whose jobs expose them to mpox or related viruses. However, pre-exposure vaccination is not recommended at this time for most clinicians in the United States or for laboratorians not performing the orthopox virus generic test to diagnose orthopox viruses, including mpox virus. More information is available at CDC mpox and Smallpox Guidance.</p> <p>Health care workers meeting any of the following criteria are considered eligible to receive mpox vaccine as Pre-Exposure Prophylaxis (PrEP). Health care workers exposed</p>																								

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	<p>to mpox virus who have not received the smallpox vaccine within the last 3 years should consider getting re-vaccinated.:</p> <ol style="list-style-type: none"> 9. Clinical laboratory personnel who perform testing to diagnose orthopox viruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopox viruses, including mpox virus 10. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopox viruses that infect humans, including mpox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains 11. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes 12. People who can get PrEP if they want to receive it include healthcare personnel who administer ACAM2000 or anticipate caring for many patients with mpox.
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Assessment

Assessment Criteria	<p>Patients determined to be at high risk for exposure shall be vaccinated with JYNNEOS. Patients who have experienced a high-risk exposure should ideally be vaccinated with JYNNEOS within 14 days of the date of exposure. Vaccination is most effective when given within 4 days of the date of the exposure. Vaccine given between 4–14 days after the date of exposure may reduce symptoms of disease but may not prevent the disease.</p>
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Subjective

	<ol style="list-style-type: none"> 1. Client presents requesting smallpox vaccine (JYNNEOS) and meets criteria above. 2. Client presents requesting 2nd dose of JYNNEOS <ol style="list-style-type: none"> a) People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting any dose of JYNNEOS. b) Persons recommended to receive JYNNEOS due to an exposure to mpox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.
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Objective

	<ol style="list-style-type: none"> 1. Immunization record reveals client has not previously completed a smallpox vaccine series with either ACAM2000 (smallpox) or JYNNEOS vaccine within the last two years for pre-exposure prophylaxis or within the last three years for post-exposure prophylaxis. 2. Immunization record indicates receipt of 1 dose of JYNNEOS at least 4 weeks ago, and patient is presenting for second dose of the primary series.
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Nursing Plan of Care

Contraindications and Precautions	<p>Screen all individuals for contraindications and precautions to JYNNEOS vaccine. Note that pregnancy and breastfeeding are not contraindications. Because JYNNEOS is non-replicating, it can be administered regardless of timing to previous live virus vaccine administration (e.g., MMR, Varicella). JYNNEOS is also safe for administration to people with HIV and atopic dermatitis.</p> <p>Consult with medical staff if the following contraindications or precautions are present. These contraindications apply to use of STANDARD OR ALTERNATIVE REGIMEN.</p>
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	<p>TABLE 3: CONTRAINDICATIONS AND PRECAUTIONS FOR USE OF JYNNEOS VACCINE (Note: JYNNEOS is formulated without preservatives. The vial stoppers are not made with natural rubber latex). More information on JYNNEOS cell line here.</p> <p>Contraindications:</p> <ul style="list-style-type: none"> • Severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine. • ALTERNATIVE REGIMEN ONLY: People of any age who have a history of developing keloid scars <p>Precautions:</p> <ul style="list-style-type: none"> • Moderate to severe acute illness, with or without fever. • History of severe allergic reaction (e.g., anaphylaxis) to gentamicin or ciprofloxacin or • History of severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein AND currently avoiding all chicken and egg products <ul style="list-style-type: none"> • After discussing risks and benefits with the patient, persons falling within these 3 categories of allergies may be vaccinated with a 30-minute observation period or vaccination may be delayed until consultation with an allergist-immunologist for persons in the last 2 categories after considering the impact of delay vaccine. • Specific Groups/Situations: <ul style="list-style-type: none"> ▪ Pregnancy and breast feeding are not contraindications to vaccination. ▪ Pediatric and Geriatric populations: there have not been adequate studies to determine safety and efficacy in those under 18* or over the age of 65. (*JYNNEOS is not licensed for administration to individuals under the age of 18; however, it has been authorized under EUA for use in individuals less than 18.). Due to an unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after receipt of vaccination before receiving an mRNA COVID-19 vaccine. If post-exposure prophylaxis is recommended, vaccination with JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine. ▪ Coadministration with tuberculin skin test: Currently, there is no data on administering JYNNEOS vaccine at the same time as the tuberculin skin test (TST). If a delay in the TST will cause substantial burden, then the TST should not be delayed. The TST can be performed at the same time as JYNNEOS vaccination, using different forearms, one on the left and one on the right. The location of each injection site should be recorded in order to read the TST from the correct forearm. If delays in the TST will not cause substantial burden, a delay of at least 4 weeks after JYNNEOS vaccination is preferred. For patients with symptoms or signs of active tuberculosis (TB), all tests and examinations for TB should be pursued without delay, regardless of JYNNEOS vaccination.
Nursing Actions	<p>Implement the following vaccine regimen if above eligibility and assessment criteria are met and no precautions or contraindications are identified:</p> <ul style="list-style-type: none"> • Prior to vaccination provide patient with a copy of Fact Sheet for Recipients and Caregivers About JYNNEOS . Smallpox/mpox Vaccine (JYNNEOS™)- English and Smallpox/mpox Vaccine (JYNNEOS™)-Spanish may be provided to augment EUA. • Per NC Statute 90-21.5, written consent is required for JYNNEOS administration of JYNNEOS in persons less than 18 years old.

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	<ul style="list-style-type: none">• Inform patient/caregiver of possible side effects and reactions. Injection site redness is common. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine.• Counsel patients that it is not known if JYNNEOS will fully protect against mpox virus infection in this outbreak. Individuals wanting to minimize their risk of infection should take additional preventive measures and immediately self-isolate should symptoms occur, such as a rash.• Health care personnel should follow routine infection control procedures when administering vaccines. Follow strict aseptic medication preparation practices. Perform hand hygiene before preparing vaccines. Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed. Avoid distractions. Some facilities have a no-interruption zone, where health care professionals can prepare medications without interruptions. Prepare medications for one patient at a time. Always follow the vaccine manufacturer’s directions, located in the package inserts.• Allow the vaccine to thaw and reach room temperature before use.• Swirl the vial gently before use for at least 30 seconds.• For individuals 18 years of age and older utilizing the ALTERNATIVE REGIMEN administer vaccine intradermally. Withdraw a dose of 0.1 mL into a sterile syringe.• Select and cleanse vaccination site 2-4 inches below the antecubital fossa (elbow) on the volar aspect of the forearm. If the volar aspect of the forearm is not an option (e.g., strong patient preference), administer vaccine intradermally at the upper back below the scapula, or at the deltoid based on patient choice.• Administer JYNNEOS intradermally into the volar surface of the forearm or other site location mentioned above.• While pulling the skin taut, position the needle bevel facing up and insert the needle at a 5-to 15-degree angle into the dermis. Slowly inject 0.1mL intradermally. A noticeable pale elevation of the skin (wheal) is desirable but not required.• If a lower-than-authorized dose is administered intradermally (e.g., patient pulled away, or leakage out of the syringe), repeat intradermal dose immediately (no minimum interval) at least 2 inches away from the site of vaccine leakage. If vaccine leakage occurs with two intradermal vaccinations on the same day, administer 0.5 mL subcutaneously.• A bandage may be placed over the injection site as needed.• NOTE: For persons who present for their second JYNNEOS vaccine dose and who are still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) administer second dose intradermally in the volar aspect of the contralateral forearm. If the volar aspect of the contralateral forearm is not an option (e.g., strong patient preference), administer vaccine intradermally based on patient choice of either the upper back below the scapula, or at the deltoid.• For persons with tattoos, avoid vaccination in the area where there is a recent (<1 month) tattoo. If tattoos cover both arms, choose a space that doesn’t have pigment (i.e., Ink). However, if the tattoo cannot be avoided, the vaccine can still be administered through the tattoo.• For individuals utilizing the STANDARD REGIMEN >12 months of age:<ul style="list-style-type: none">○ Administer 0.5 ml JYNNEOS subcutaneously by pinching up fatty tissue over the triceps area in the upper arm and insert the needle at a 45-degree angle.○ Use a 23-25g, 5/8" needle.
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	<ul style="list-style-type: none"> • For individuals utilizing the STANDARD REGIMEN with infants <12 months of age: <ul style="list-style-type: none"> ○ Administer 0.5ml JYNNEOS subcutaneously by pinching up fatty tissue over the anterolateral thigh and insert the needle at a 45-degree angle. ○ Use a 23-25g, 5/8" needle. • Observe Patients after Vaccination for 15 minutes unless patient meets criteria listed above under "Precautions". Monitor all patients after vaccination for the occurrence of immediate adverse reactions, including syncope. • Counsel the patient to return in 28 days (4 weeks) for the second dose if the dose administered is the first dose. <ul style="list-style-type: none"> • Once the vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. After thawing, the total time stored at +2°C to +8°C (+36°F to +46°F) should not exceed 8 weeks. • Document each patient's vaccine administration information and follow up in the following locations: Electronic medical record/North Carolina Immunization Registry (NCIR)- record the date the vaccine was administered, manufacturer and lot number, the vaccination site and route, the name and title of the person administering the vaccine. Race, ethnicity, and gender and are now required fields in NCIR and should be reviewed and updated to ensure accurate documentation for the JYNNEOS recipient. For tracking purposes, ensure doses are documented from live inventory in NCIR (do not enter historically). • If the vaccine was not administered, record reason (s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal). • Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs. • Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov. • Instruct patient to call clinic, or their health care provider with any questions and/or problems. • Inform vaccine recipient of the importance of completing the two dose vaccination series (at least 28 days apart) for first time vaccine recipients. • Vaccines inadvertently administered intramuscularly (IM) can be considered valid doses and do not need to be repeated. IM doses need to be reported to the manufacturer at drug.safety@bavarian-nordic.com.
Follow-up	<p>VAERS Reporting: Healthcare providers are required to report to VAERS adverse events found in the Reportable Events Table (RET). For events not included in the RET, healthcare providers are encouraged to report any additional clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event.</p> <p>Anaphylaxis Management: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis.</p> <p>Syncope: Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.</p>
Criteria for Notifying the physician/APP	

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Criteria for Notifying the physician/APP	<ol style="list-style-type: none">1. Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.2. Consult with physician/ advanced practice provider if the patient reports any contraindications or precautions to the vaccine prior to administration.
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Approved by: _____
(Signature of physician/APP)

Date approved (or last reviewed): _____